

CLAIMS:

1. A method of treatment and/or prevention of an inflammatory condition in a fluid-containing organ having a natural exterior orifice, the method comprising administering a pharmaceutical composition comprising an anti-inflammatory agent to the organ via the exterior orifice, said composition further comprising a vehicle that comprises (a) an amphipathic oil that is water dispersible and ethanol insoluble, (b) microcrystalline wax and (c) a pharmaceutically acceptable non-aqueous carrier.
2. The method of Claim 1 wherein the fluid-containing organ is an udder of a milk producing animal, and wherein the composition is administered by intramammary infusion.
3. The method of Claim 2 wherein the inflammatory condition is associated with mastitis.
4. The method of Claim 1 wherein the fluid-containing organ is an ear of a subject, and wherein the composition is administered by infusion into the ear.
5. The method of Claim 4 wherein the inflammatory condition is associated with an otic disorder selected from the group consisting of otitis externa, otitis media, otorrhea, acute mastoiditis, infections related to otic surgical procedures, otosclerosis, otalgia, otic pain, otic inflammation, otic bleeding, Lermoyez's syndrome, Meniere's disease, vestibular neuronitis, benign paroxysmal positional vertigo, herpes zoster oticus, Ramsay Hunt's syndrome, viral neuronitis, ganglionitis, geniculate herpes, labyrinthitis, including purulent labyrinthitis and viral endolymphatic labyrinthitis, perilymph fistulas, presbycusis, drug-induced ototoxicity, acoustic neuromas, aerotitis media, infectious myringitis, bullous myringitis, otic neoplasm, squamous cell carcinoma, basal cell carcinoma, other otic cancers, pre-cancerous otic conditions, nonchromaffin paragangliomas, chemodectomas, glomus jugulare tumors, glomus tympanicum tumors, perichondritis, aural eczematoid dermatitis, malignant external otitis, subperichondrial hematoma, ceruminomas, impacted cerumen, sebaceous cysts, osteomas, keloids, tinnitus, vertigo, tympanic membrane infection, tympanitis, otic furuncles, petrositis, conductive and

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- sensorineural hearing loss, epidural abscess, lateral sinus thrombosis, subdural empyema, otitic hydrocephalus, Dandy's syndrome, bullous myringitis, diffuse external otitis, foreign bodies, keratosis obturans, otomycosis, trauma, acute barotitis media, acute eustachian tube obstruction, postsurgical otalgia, and complications associated therewith.
- 10      6. The method of Claim 4 wherein the inflammatory condition is associated with an otic disorder selected from the group consisting of otitis externa, otitis media, otorrhea, and infections having an inflammatory component that are related to an otic surgical procedure.
- 15      7. The method of Claim 1 wherein the anti-inflammatory agent is selected from the group consisting of aceclofenac, acemetacin, *e*-acetamidocaproic acid, acetaminophen, acetaminosalol, acetanilide, acetylsalicylic acid, *S*-adenosylmethionine, alclofenac, alclometasone, alfentanil, algestone, allylprodine, alminoprofen, aloxiprin, alphaprodine, aluminum bis(acetylsalicylate), amcinonide, amfenac, aminochlorthenoxazin, 3-amino-4-hydroxybutyric acid, 2-amino-4-picoline, aminopropylon, aminopyrine, amixetrine, ammonium salicylate, ampiroxicam, amtolmetin guacil, anileridine, antipyrine, antafenine, apazone, beclomethasone, bendazac, benorylate, benoxaprofen, benzpiperylon, benzydamine, benzylmorphine, bermoprofen, betamethasone, betamethasone-17-valerate, bezitramide,  $\alpha$ -bisabolol, bromfenac, *p*-bromoacetanilide, 5-bromosalicylic acid acetate, bromosaligenin, buketin, bucloxic acid, bucolome, budesonide, bufexamac, bumadizon, buprenorphine, butacetin, butibufen, butorphanol, carbamazepine, carbiphene, carprofen, carsalam, chlorobutanol, chloroprednisone, chlorthenoxyazin, choline salicylate, cinchophen, cinmetacin, ciramadol, clidanac, clobetasol, clocortolone, clometacin, clonitazene, clonixin, clopirac, cloprednol, clove, codeine, codeine methyl bromide, codeine phosphate, codeine sulfate, cortisone, cortivazol, cropropamide, crotethamide, cyclazocine, deflazacort, dehydrotestosterone, desomorphine, desonide, desoximetasone, dexamethasone, dexamethasone-21-isonicotinate, dexoxadrol, dextromoramide, dextropropoxyphene, deoxycorticosterone, dezocine, diamamide, diamorphine, diclofenac, difenamizole, difenpiramide, diflorasone, diflucortolone, diflunisal,
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difluprednate, dihydrocodeine, dihydrocodeinone enol acetate, dihydromorphine,  
dihydroxyaluminum acetylsalicylate, dimenoxadol, dimepheptanol,  
dimethylthiambutene, dioxaphetyl butyrate, dipipanone, diprocetyl, dipyrone,  
ditazol, droxicam, emorfazole, enfenamic acid, enoxolone, epirizole,  
5 eptazocine, etersalate, ethenzamide, ethoheptazine, ethoxazene,  
ethylmethylthiambutene, ethylmorphine, etodolac, etofenamate, etonitazene,  
eugenol, felbinac, fenbufen, fenclozic acid, fendosal, fenoprofen, fentanyl,  
fentiazac, fepradinol, feprazole, floctafenine, fluazacort, flucoronide,  
10 flufenamic acid, flumethasone, flunisolide, flunixin, flunoxaprofen, fluocinolone  
acetone, fluocinonide, fluocinolone acetonide, fluocortin butyl, fluocortolone,  
fluoresone, fluorometholone, fluperolone, flupirtine, fluprednidene,  
fluprednisolone, fluproquazone, flurandrenolide, flurbiprofen, fluticasone,  
formocortal, fosfosal, gentisic acid, glafenine, glucametacin, glycol salicylate,  
guaiaculene, halcinonide, halobetasol, halometasone, haloprednone, heroin,  
15 hydrocodone, hydrocortamate, hydrocortisone, hydrocortisone acetate,  
hydrocortisone succinate, hydrocortisone hemisuccinate, hydrocortisone 21-  
lysinate, hydrocortisone cypionate, hydromorphone, hydroxypethidine, ibufenac,  
ibuprofen, ibuproxam, imidazole salicylate, indomethacin, indoprofen,  
isofezolac, isoflupredone, isoflupredone acetate, isoladol, isomethadone,  
20 isonixin, isoxepac, isoxicam, ketobemidone, ketoprofen, ketorolac,  
*p*-lactophenetide, lefetamine, levallorphan, levorphanol, levophenacyl-morphan,  
lofentanil, lonazolac, lornoxicam, loxoprofen, lysine acetylsalicylate,  
mazipredone, meclofenamic acid, medrysone, mefenamic acid, meloxicam,  
meperidine, meprednisone, meptazinol, mesalamine, metazocine, methadone,  
methotripeprazine, methylprednisolone, methylprednisolone acetate,  
25 methylprednisolone sodium succinate, methylprednisolone suleptnate,  
metiazinic acid, metofoline, metopon, mofebutazone, mofezolac, mometasone,  
morazone, morphine, morphine hydrochloride, morphine sulfate, morpholine  
salicylate, myrophine, nabumetone, nalbuphine, nalorphine, 1-naphthyl  
salicylate, naproxen, narceine, nefopam, nicomorphine, nifenazone, niflumic  
30 acid, nimesulide, 5'-nitro-2'-propoxyacetanilide, norlevorphanol, normethadone,  
normorphine, norpipanone, olsalazine, opium, oxaceprol, oxametacaine,  
oxaprozin, oxycodone, oxymorphone, oxyphenbutazone, papaveretum,

- paramethasone, paranyline, parsalmide, pentazocine, perisoxal, phenacetin,  
phenadoxone, phenazocine, phenazopyridine hydrochloride, phenocoll,  
phenoperidine, phenopyrazone, phenomorphan, phenyl acetylsalicylate,  
phenylbutazone, phenyl salicylate, phenyramidol, pikedoprofen, piminodine,  
5 pipebuzone, piperylone, piprofen, pirazolac, piritramide, piroxicam,  
pranoprofen, prednicarbate, prednisolone, prednisone, prednival, prednylidene,  
proglumetacin, proheptazine, promedol, propacetamol, properidine, propiram,  
propoxyphene, propyphenazone, proquazone, protizinic acid, proxazole,  
10 ramifenazone, remifentanil, rimazolium metilsulfate, salacetamide, salicin,  
salicylamide, salicylamide *o*-acetic acid, salicylic acid, salicylsulfuric acid,  
salsalate, salverine, simetride, sufentanil, sulfasalazine, sulindac, superoxide  
dismutase, suprofen, suxibuzone, talniflumate, tenidap, tenoxicam,  
terofenamate, tetrandrine, thiazolinobutazone, tiaprofenic acid, tiaramide,  
tilidine, tinoridine, tixocortol, tolfenamic acid, tolmetin, tramadol,  
15 triamcinolone, triamcinolone acetonide, tropesin, viminol, xenbucin,  
ximoprofen, zaltoprofen and zomepirac.
8. The method of Claim 1 wherein the anti-inflammatory agent is a selective COX-2 inhibitor.
9. The method of Claim 8 wherein the selective COX-2 inhibitor is selected from  
20 the group consisting of deracoxib, parecoxib, celecoxib, valdecoxb, rofecoxib,  
etoricoxib, lumiracoxib, 2-(3,5-difluorophenyl)-3-[4-(methylsulfonyl)phenyl]-2-  
cyclopenten-1-one, (S)-6,8-dichloro-2-(trifluoromethyl)-2H-1-benzopyran-3-  
carboxylic acid, 2-(3,4-difluorophenyl)-4-(3-hydroxy-3-methyl-1-butoxy)-5-[4-  
25 (methylsulfonyl)phenyl]-3-(2H)-pyridazinone, 4-[5-(4-fluorophenyl)-3-  
(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide, 4-[5-(phenyl)-3-  
(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide, salts and prodrugs  
thereof.
10. A pharmaceutical composition comprising a vehicle that comprises (a) an  
amphipathic oil that is water dispersible and ethanol insoluble, (b)  
30 microcrystalline wax and (c) a pharmaceutically acceptable non-aqueous carrier;  
said vehicle having stably dispersed therein an anti-inflammatory agent in an  
anti-inflammatorily effective amount.

11. The composition of Claim 10 wherein the anti-inflammatory agent is selected from the group consisting of aceclofenac, acemetacin, *e*-acetamidocaproic acid, acetaminophen, acetaminosalol, acetanilide, acetylsalicylic acid, *S*-adenosylmethionine, alclofenac, alclometasone, alfentanil, algestone, allylprodine, alminoprofen, aloxiprin, alphaprodine, aluminum bis(acetylsalicylate), amcinonide, amfenac, aminochlorthenoxazin, 3-amino-4-hydroxybutyric acid, 2-amino-4-picoline, aminopropylon, aminopyrine, amixetrine, ammonium salicylate, ampiroxicam, amtolmetin guacil, anileridine, antipyrine, antrafenine, apazone, beclomethasone, bendazac, benorylate, 10 benoxaprofen, benzpiperylon, benzydamine, benzylmorphine, bermoprofen, betamethasone, betamethasone-17-valerate, bezitramide,  $\alpha$ -bisabolol, bromfenac, *p*-bromoacetanilide, 5-bromosalicylic acid acetate, bromosaligenin, bucetin, bucloxic acid, bucolome, budesonide, bufexamac, bumadizon, buprenorphine, butacetin, butibufen, butorphanol, carbamazepine, carbiphene, 15 carprofen, carsalam, chlorobutanol, chloroprednisone, chlorthenoxyzin, choline salicylate, cinchophen, cinmetacin, ciramadol, clidanac, clobetasol, clo cortolone, clometacin, clonitazene, clonixin, clopirac, cloprednol, clove, codeine, codeine methyl bromide, codeine phosphate, codeine sulfate, cortisone, cortivazol, 20 cropropamide, crotethamide, cyclazocine, deflazacort, dehydrotestosterone, desomorphine, desonide, desoximetasone, dexamethasone, dexamethasone-21-isonicotinate, dexoxadrol, dextromoramide, dextropropoxyphene, deoxycorticosterone, dezocine, diamprodide, diamorphone, diclofenac, difenamizole, difenpiramide, diflorasone, diflucortolone, diflunisal, 25 difluprednate, dihydrocodeine, dihydrocodeinone enol acetate, dihydromorphine, dihydroxyaluminum acetylsalicylate, dimenoxadol, dimepheptanol, dimethylthiambutene, dioxaphetyl butyrate, dipipanone, diprocetyl, dipyrone, ditazol, droxicam, emorfazole, enfenamic acid, enoxolone, epirizole, eptazocine, etersalate, ethenzamide, ethoheptazine, ethoxazene, ethylmethylthiambutene, ethylmorphine, etodolac, etofenamate, etonitazene, 30 eugenol, felbinac, fensufen, fenclozic acid, fendosal, fenoprofen, fentanyl, fentiazac, fepradinol, feprazole, floctafenine, fluazacort, flucoronide, flufenamic acid, flumethasone, flunisolide, flunixin, flunoxyprofen, fluocinolone

acetonide, fluocinonide, fluocinolone acetonide, fluocortin butyl, fluocortolone,  
fluoresone, fluorometholone, fluperolone, flupirtine, fluprednidene,  
fluprednisolone, fluproquazone, flurandrenolide, flurbiprofen, fluticasone,  
formocortal, fosfosal, gentisic acid, glafenine, glucametacin, glycol salicylate,  
5 guaiazulene, halcinonide, halobetasol, halometasone, haloprednone, heroin,  
hydrocodone, hydrocortamate, hydrocortisone, hydrocortisone acetate,  
hydrocortisone succinate, hydrocortisone hemisuccinate, hydrocortisone 21-  
lysinate, hydrocortisone cypionate, hydromorphone, hydroxypethidine, ibufenac,  
ibuprofen, ibuproxam, imidazole salicylate, indomethacin, indoprofen,  
10 isofezolac, isoflupredone, isoflupredone acetate, isoladol, isomethadone,  
isonixin, isoxepac, isoxicam, ketobemidone, ketoprofen, ketorolac,  
*p*-lactophenetide, lefetamine, levallorphan, levorphanol, levophenacyl-morphan,  
lofentanil, lonazolac, lornoxicam, loxoprofen, lysine acetylsalicylate,  
mazipredone, meclofenamic acid, medrysone, mefenamic acid, meloxicam,  
15 meperidine, meprednisone, meptazinol, mesalamine, metazocine, methadone,  
methotriimeprazine, methylprednisolone, methylprednisolone acetate,  
methylprednisolone sodium succinate, methylprednisolone suleptnate,  
metiazinic acid, metofoline, metopon, mofebutazone, mofezolac, mometasone,  
morazone, morphine, morphine hydrochloride, morphine sulfate, morpholine  
20 salicylate, myrophine, nabumetone, nalbuphine, nalorphine, 1-naphthyl  
salicylate, naproxen, narceine, nefopam, nicomorphine, nifenazone, niflumic  
acid, nimesulide, 5'-nitro-2'-propoxyacetanilide, norlevorphanol, normethadone,  
normorphine, norpipanone, olsalazine, opium, oxaceprol, oxametacaine,  
oxaprozin, oxycodone, oxymorphone, oxyphenbutazone, papaveretum,  
25 paramethasone, paranyline, parsalmide, pentazocine, perisoxal, phenacetin,  
phenadoxone, phenazocine, phenazopyridine hydrochloride, phenocoll,  
phenoperidine, phenopyrazone, phenomorphan, phenyl acetylsalicylate,  
phenylbutazone, phenyl salicylate, phenyramidol, piketoprofen, piminodine,  
pipebuzone, piperylone, pirazolac, piritramide, piroxicam, pirprofen,  
30 pranoprofen, prednicarbate, prednisolone, prednisone, prednival, prednylidene,  
proglumetacin, proheptazine, promedol, propacetamol, properidine, propiram,  
propoxyphene, propyphenazone, proquazone, protizinic acid, proxazole,  
ramifenazone, remifentanil, rimazolium metilsulfate, salacetamide, salicin,

salicylamide, salicylamide *o*-acetic acid, salicylic acid, salicylsulfuric acid, salsalate, salverine, simetride, sufentanil, sulfasalazine, sulindac, superoxide dismutase, suprofen, suxibuzone, talniflumate, tenidap, tenoxicam,  
5 terofenamate, ttrandrine, thiazolinobutazone, tiaprofenic acid, tiaramide, tilidine, tinoridine, tixocortol, tolfenamic acid, tolmetin, tramadol, triamcinolone, triamcinolone acetonide, tropesin, viminol, xenbucin, ximoprofen, zaltoprofen and zomepirac.

12. The composition of Claim 10 wherein the anti-inflammatory agent is a steroid.
13. The composition of Claim 10 wherein the anti-inflammatory agent is an NSAID.
- 10 14. The composition of Claim 10 wherein the anti-inflammatory agent is a selective COX-2 inhibitor.
15. The composition of Claim 14 wherein the selective COX-2 inhibitor is selected from the group consisting of deracoxib, parecoxib, celecoxib, valdecoxib, rofecoxib, etoricoxib, lumiracoxib, 2-(3,5-difluorophenyl)-3-[4-(methylsulfonyl)phenyl]-2-cyclopenten-1-one, (S)-6,8-dichloro-2-(trifluoromethyl)-2H-1-benzopyran-3-carboxylic acid, 2-(3,4-difluorophenyl)-4-(3-hydroxy-3-methyl-1-butoxy)-5-[4-(methylsulfonyl)phenyl]-3-(2H)-pyridazinone, 4-[5-(4-fluorophenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide, 4-[5-(phenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide, salts and prodrugs thereof.  
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